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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,597	12/19/2000	Bruce J. Barclay	VASC 1020-1	3762
22470	7590	11/17/2004	EXAMINER	
HAYNES BEFFEL & WOLFELD LLP P O BOX 366 HALF MOON BAY, CA 94019			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 11/17/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/740,597

Applicant(s)

BARCLAY ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-38 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-36 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28-30,32,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi (5676685) in view of Kropf '849. Razavi shows (Fig. 13) a coiled stent body **12** covered by a graft material **18**. It can also be seen there is a protective layer **16** that is removable. Razavi also discloses the body or core coil is made of metal, such as NiTi (col. 2, lines 37-44). Razavi discloses that a vasodilator drug can be incorporated within the sleeve, col. 3, lines 22-25. NO generators are well known in the art as common vasodilators. Razavi discloses that the stent is delivered inside a vessel of a patient, col. 2, lines 15-17. Razavi additionally teaches the protective layer can be biodegradable, col. 3, lines 13-17. However, Razavi fails to disclose the coil as having spaced apart parallel side elements joined by connector elements. Kropf teaches a coiled stent (Fig. 5) spaced apart parallel side elements joined by connector elements. Kropf teaches that the structural design enables the prosthesis to be deployed in a small profile reducing the likelihood of vessel trauma, col. 3, lines 8-13. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the stent of Razavi in order to provide a stent with good flexibility and a small profile for delivery having more radial support.

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Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of Kropf '849 as applied to claim 28 above, and further in view of Khosravi et al. (5824054). Razavi as modified by Kropf is explained supra. However, Razavi in view of Kropf fail to the graft material as ptfe. Khosravi discloses the sleeve material is made of PTFE, col. 5, lines 1-10. It would have been obvious to one of ordinary skill in the art to substitute the graft material and use ptfe as taught by Khosravi with the stent of Razavi as modified by Kropf in order to provide a more naturally responding graft material that can permit release of the drug and maintain pressure differentials.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of Kropf '849 as applied to claim 28 above, and further in view of Herzog et al. (WO 98/08482). Razavi as modified by Kropf is explained supra. However, Razavi in view of Kropf fail to disclose the drug being encapsulated. Herzog teaches the agent can also be encapsulated, page 12, line 11. It would have been obvious to one of ordinary skill in the art to modify the means of delivering the drug and encapsulating it as taught by Herzog in the stent of Razavi as modified by Kropf in order to provide a more controlled release of the NO.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of Kropf '849 as applied to claim 28 above, and further in view of Ragheb et al. (5873904). Razavi as modified by Kropf is explained supra. However, Razavi in view of Kropf fail to disclose a second drug being used in conjunction with the NO generator. Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill

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in the art to use a second agent as taught by Ragheb with the stent of Razavi as modified by Kropf in order to provide a greater therapeutic medical device with multiple treatment capabilities.

### ***Response to Arguments***

Applicant's arguments with respect to claim 28 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/10/04 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian E. Pellegrino

Primary Examiner  
TC 3700, AU 3738

A handwritten signature in cursive script that reads "Brian E. Pellegrino". The signature is written in dark ink and is located at the bottom of the page.